

## **Remarks:**

Claims 1-34 are under examination in the Subject Application. Original claims 35-49 were withdrawn in response to the Examiner's previously-issued restriction requirement and remain so in the present Response. In the present Response, Applicants amend claims 21 and 32, cancel the second claim numbered "31", and add new claims 50 through 52.

In the numbered sections below, Applicants address the various points made in the Office Action.

### **1. Renumbering of Claims**

The Examiner notes in the Office Action that the Subject Application includes two claims numbered "31". In order to simplify correction of this inadvertent typographical error, Applicants herein cancel the second original claim 31 and add new claim 50 that is identical to the canceled claim. To account for the addition of claim 50, claim 32 is amended to also refer to the alloy recited in new claim 50.

### **2. Claim Rejections – 35 U.S.C. § 102**

The Examiner rejects claims 21, 24, 25, and 50 under 35 U.S.C. § 102(a) as being anticipated by the MP35N alloy material shipped to Fort Wayne Metals on December 10, 2002 (the "shipped MP35N alloy"), as described in the Declaration submitted on November 18, 2005. Claims 24, 25, and 50 depend directly from claim 21, which is an independent claim. The Examiner argues that the shipped MP35N alloy inherently would have been "substantially free of titanium nitride and mixed metal carbonitride inclusions," as is recited in claim 21.

In the present Response, Applicants amend claim 21 to recite that the claimed alloy also includes "at least one of at least 0.05 weight percent aluminum, at least 5 ppm calcium, at least 5 ppm magnesium, and at least 5 ppm cerium". Support for including aluminum in the alloy is provided in, for example, paragraphs [0045] and [0046] of the Subject Application. Support for including ppm levels of calcium in the alloy is provided in Example 3 of the Subject Application, wherein providing ppm levels of calcium, magnesium, or cerium in the alloy resulted in alloy microstructures having no

appreciable levels of titanium nitride or mixed metal carbonitride inclusions. Instead, as described in paragraph [0074] and demonstrated in the table of Figure 21 of the Subject Application, inclusions in the experimental alloys produced with calcium, magnesium, or cerium in Example 3 were almost exclusively oxides of the particular deoxidizing species used (calcium, magnesium, or cerium).

It is believed that the recited addition of aluminum, calcium, magnesium, and/or cerium and the resultant formation of oxide inclusions from such oxidizers help to inhibit formation of problematic levels of titanium nitride and mixed metal carbonitride inclusions in MP35N-type alloys. Also, it has been determined that oxide inclusions having the particular morphology and/or size produced in MP35N-type alloys as a result of the recited inclusions of aluminum, calcium, magnesium, and/or cerium are well tolerated when cold drawing or forging the alloys. In other words, experimental alloys described in the Subject Application including the aluminum, calcium, magnesium, and/or cerium oxide inclusions did not exhibit an unacceptable tendency to develop surface defects or to fracture or crack during cold drawing to wire or forging. Thus, the present inventors believe that including low levels of at least one of the recited deoxidizing species in the alloys helps to inhibit the formation of problematic titanium nitride and mixed metal carbonitride inclusions, while producing well-tolerated oxide inclusions.

The shipped MP35N alloy did not include the levels of aluminum, calcium, magnesium, and/or cerium now recited in claim 21. For at least that reason, the alloy recited in claim 21, as amended herein, is novel relative to the shipped MP35N alloy. Dependent claims 24, 25, and 50 ultimately depend from claim 21 and, therefore, it follows that the alloys recited in those claims also are novel relative to the shipped MP35N alloy.

Accordingly, the Examiner's should withdraw the rejection of claims 21, 24, and 25.

### 3. Claim Rejections – 35 U.S.C. § 103

#### a. The Rejection of Claims 1-11, 16-25, and 30-34

The Examiner rejects claims 1-11, 16-25, and 30-34 under 35 U.S.C. § 103(a) as having been obvious over the alloy composition of ASTM F 562-02 in view of Cockcroft, et al., "Inclusions and the EB Refining of Superalloys" ("Cockcroft"). This group of rejected claims includes independent claims 1 and 21. ASTM F 562-02 is the alloy specification for conventional wrought MP35N for surgical implants. Cockcroft discusses techniques, including electron beam melting and filtration, for reducing or eliminating TiN inclusions and certain other inclusions in certain alloys. The Examiner asserts that "[i]t would have been obvious to one of ordinary skill in the art to modify the superalloy composition of ASTM F 562-02 by reducing the nitrogen content using electron beam melting in order to eliminate TiN inclusions as taught by Cockcroft".

The Examiner bears the initial burden to establish a *prima facie* case that the claimed invention would have been obvious. *In re Piasecki*, 745, F.2d 1468, 1472 (Fed. Cir. 1984); MPEP § 2142. To establish such a *prima facie* case, the Examiner must satisfy three requirements. First, the prior art relied upon, plus the knowledge generally available in the art at the time of the invention, must include some suggestion or incentive that would have motivated one of ordinary skill to modify a reference or combine the references in the fashion suggested by the Examiner. *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). Second, the proposed modification to the prior art must have had a reasonable expectation of success, determined from the perspective of the ordinarily skilled artisan at the time the invention was made. *See Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209 (Fed. Cir. 1991). Third, the asserted prior art reference or combination of references must teach or suggest all of the limitations of the rejected claim. *See In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970).

In light of this framework, the Examiner's reliance on Cockcroft is misplaced. Cockcroft focuses on reducing the level of inclusions in a specific alloy, IN718 alloy, also known as Inconel 718 alloy. IN718 alloy is the only alloy identified and tested in Cockcroft, and Tables 1 - 3 and Figures 2-6 and 8 of Cockcroft specifically relate solely to IN718 alloy.

As is known in the art, IN718 alloy includes 50 - 55 wt. % nickel, 2.8 -3.3 wt. % molybdenum, and no more than 1 wt. % cobalt, among other alloying additions. In contrast, the composition of MP35N alloy, as recited in ASTM F 562-02, includes 33.0 - 37.0 wt. % nickel, 9.0 - 10.5 wt. % molybdenum, and “balance” cobalt. Considering the allowed ranges of the various alloying additions in the specification for MP35N alloy, the alloy includes at least about 29 wt. % cobalt.

Therefore, the composition of MP35N alloy differs substantially from IN718 alloy. Given these significant differences, an expectation would not have existed that the techniques described in Cockcroft would successfully reduce TiN and other inclusions in MP35N alloy. In other words, one of ordinary skill would not look to references disclosing techniques applied to IN718 alloy when considering modifications to MP35N alloy or, for that matter.

Moreover, as noted above, establishing a *prima facie* case of obviousness requires that there existed some motivation, either within the cited references or within the general knowledge in the art, to combine the references as suggested by the Examiner. The Examiner states in the Office Action that one of ordinary skill would have modified the composition of ASTM F 562-02 to reduce the nitrogen content of the alloy using electron beam melting “to eliminate TiN inclusions as taught by Cockcroft”. This, however, does not identify why one would have been motivated to so modify the ASTM F 562-02 alloy composition. Instead, it only identifies the end result the Examiner apparently concludes would occur on electron beam melting an alloy having the composition of ASTM F 562-02. The Examiner’s rationale for combining the references does not answer the question critical to establishing a *prima facie* case: Why would one go to the added work and expense of electron beam melting MP35N alloy, assuming *arguendo* that doing so actually would reduce TiN inclusions in the alloy?

In the present case, the present inventors were those who initially identified a link between the performance of MP35N alloy in certain applications and the presence and morphology of inclusions in the alloy. As explained in paragraph [0003] of the Subject Application:

[0003] certain technical problems may be encountered during the manufacture of MP35N alloy for use in pacing leads and other surgical implant applications. In particular, problematic surface defects may appear when cold drawing the alloy to wire. When drawing the alloy to small-gauge wire for use as pacing leads, for example, surface defects are most likely to develop during the late stages of the drawing process, when the wire approaches the 0.007 inch diameter final size typically used for such applications. Drawing-related surface defects are particularly problematic because they may appear after significant time and money is invested in the product. As the wire approaches a small diameter, the surface defects may cause the wire to fracture during cold drawing. This results in lower process yields during wire production, which can significantly increase the cost of the wire. Pacing leads and other surgical implants formed from MP35N alloy wire having surface defects also may have reduced fatigue resistance and may be susceptible to fracture. The resultant reduced service life may require premature replacement of the implant.

As explained in paragraphs [0031] and [0032] of the Subject Application, the present inventors discovered that it was the presence of certain inclusions in MP35N alloy that is the source of the alloy's poor performance:

[0031] It has been determined that the poor performance of MP35N alloy during cold drawing and forging is due to the presence of large, hard titanium nitride (TiN) inclusions. Also, in MP35N alloys including relatively high nitrogen levels, large, hard cuboidal mixed metal carbonitride inclusions may form in the alloys. The mixed metal carbonitrides are principally titanium and chromium carbonitrides. The principal failure mechanism of the conventional MP35N alloy upon drawing and forging is fatigue initiation at the particulate inclusions. The TiN and

mixed metal carbonitride inclusions may form during solidification of the alloy after melting, and the particles cannot be removed or broken up by subsequent heat treatment or thermomechanical processing. Instead, it has been determined that the inclusions are retained in their as-cast size in the final product.

[0032] The hard TiN and mixed metal carbonitride particles damage the drawing die during cold drawing of conventional MP35N material. Wire drawn through a damaged die may have surface defects in the form of scratches on the wire surface. Die damage and resulting wire surface defects significantly reduce yield. As the drawn wire becomes smaller in diameter, the nitride and carbonitride particles take up a larger portion of the wire cross-section and, therefore, weaken the material, thus creating fractures during drawing. The particles also act as stress raisers during fatigue loading and contribute to the initiation of fatigue cracks, which can result in the premature failure of the material and the associated device.

Prior to the foregoing discoveries by the inventors, there existed no clear understanding of the failure mechanism in pacemaker lead wires and other wire formed from MP35N alloy used in surgical implant applications. Conversely, there also existed no motivation or suggestion in the art to inhibit the content of inclusions in the MP35N-type alloys by reducing nitrogen content below the conventional levels of about 50 ppm. Indeed, that an understanding of the failure mechanism did not exist is confirmed by the current specification for MP35N wire for implant applications, ASTM F 562-02, which lacks any allowable range or maximum concentration for nitrogen.

Because prior to the present inventors' discovery there existed no motivation or suggestion to reduce nitrogen content in MP35N alloy below conventional levels, one would not have been motivated to modify the then-existing techniques for producing MP35N alloy so as to reduce nitrogen content and, thereby, the level of TiN and other

nitrogen-containing inclusions. Accordingly, the Examiner has not identified the required motivation or suggestion to modify ASTM F 562-02 based on Cockcroft as proposed in the Office Action. In fact, no such motivation or suggestion existed before the present inventors' discovery.

Thus, the Examiner has not established a *prima facie* case that the invention recited in claim 1 would have been obvious because (1) there existed no motivation or suggestion to combine ASTM F 562-02 and Cockcroft, and (2) there would have existed no reasonable expectation that combining the references would achieve the result Cockcroft teaches for the compositionally dissimilar IN718 alloy. Therefore, the Examiner should withdraw the rejection of claim 1.

Dependent claims 2-11 and 16-20 each directly or ultimately depend from claim 1. Because it has been shown herein that the Examiner has not established a *prima facie* case that the alloy of claim 1 would have been obvious, it follows that the Examiner also has not established a *prima facie* case that the alloys recited in any of claims 2-11 would have been obvious. Therefore, the Examiner also should withdraw his rejections of claims 2-11 and 16-20.

With regard to claim 21, it has been shown above that the Examiner has not established a *prima facie* case that the claimed alloy composition would have been obvious. However, even assuming *arguendo* that the Examiner has properly combined ASTM F 562-02 and Cockcroft in the § 103(a) rejection of claim 21, the combination of references does not result in the alloy of amended claim 21 inasmuch as claim 21 now recites that the alloy includes "at least one of at least 0.05 weight percent aluminum, at least 5 ppm calcium, at least 5 ppm magnesium, and at least 5 ppm cerium." This element of claim 21 is neither disclosed nor suggested by combining ASTM F 562-02 and Cockcroft. Accordingly, the Examiner should withdraw his rejection of claim 21 based on the combination of ASTM F 562-02 and Cockcroft.

Dependent claims 22-25, 30, and 31 each depend directly from claim 21. Because it has been shown that the Examiner has not properly combined ASTM F 562-02 and Cockcroft in rejecting claim 21, it necessarily follows that the Examiner has not shown dependent claims 22 -25, 30, and 31 to have been obvious over this combination

of references. Therefore, the Examiner should withdraw this rejection of claims 22-25, 30, and 31.

Dependent claim 32 multiply depends from claims 1-31. Claims 1-31 include independent claims 1 and 21, which in the discussion above have been shown to be patentable relative to the asserted combination of ASTM F 562-02 and Cockcroft. Dependent claims 33 and 34 depend from claim 32. Given the relation between the claims, it follows that the Examiner has not established a *prima facie* case based on ASTM F 562-02 and Cockcroft that the inventions of claims 32-34 would have been obvious. Therefore, these rejections should be withdrawn.

**b. The Rejection of Claims 12, 14, 26, and 28**

The Examiner rejects claims 12, 14, 26, and 28 under 35 U.S.C. § 103(a) as having been obvious over ASTM F 562-02 in view of Cockcroft, and further in view of U.S. Patent No. 3,816,106 to Snape ("Snape"). The Examiner argues that Snape suggests adding 0.02 - 1 wt. % aluminum to increase strength and improve hot workability of the alloy, and also suggests adding 20 - 50 ppm magnesium to improve hot workability.

Claims 12 and 26 depend from claims 1 and 21, respectively, and add the limitation that the alloy includes 0.05 - 0.15 wt. % aluminum. Claims 14 and 28 also depend from claims 1 and 21, respectively, and add the limitation that the alloy includes 5 - 50 ppm magnesium. The Examiner apparently relies on the combination of ASTM F 562-02 and Cockcroft to establish all of the constituents of the claimed alloys but for the recited aluminum and magnesium contents. The Examiner apparently concludes that Snape would have suggested further modifying the alloy compositions recited in ASTM F 562-02 to include the aluminum and magnesium contents recited in the rejected claims.

The Examiner's rejections cannot be maintained. First, Applicants have shown above that the Examiner has not established a *prima facie* case that the alloys recited in claim 1 and claim 21 would have been obvious. The addition of Snape does not remedy this. Since the Examiner has not established that the inventions of claims 1 and 21 would have been obvious (and since the Examiner's additional reliance on Snape



does not change this), it follows that claims 12, 14, 26 and 28 also have not been shown to be unpatentable.

Second, Snape would not have motivated or suggested to one of ordinary skill including 0.02 - 1 wt. % aluminum or 20 - 50 ppm magnesium in an alloy having the compositions as recited in ASTM F 562-02. For example, the Snape alloy includes 22 - 40 wt. % chromium, while the alloy of ASTM F 562-02 includes 19.0 - 21.0 wt. % chromium. The Snape alloy also includes 10 - 25 wt. % nickel, while the alloy of ASTM F 562-02 includes 33.0 - 37.0 wt. % nickel. Also, and significantly, the Snape alloy includes at least 15 wt. % iron, while the alloy of ASTM F 562-02 includes maximum 1.0 wt. % iron. The Snape alloy differs so substantially from the alloy of ASTM F 562-02 that one would not look to Snape for teachings in any way pertinent or useful to modifying the alloy recited in the claims. Viewed in another way, given the substantial compositional differences, one of ordinary skill would not perceive in the teachings of Snape any motivation or a suggestion to modify the alloy of ASTM F 562-02 in any way.

Accordingly, the Examiner should withdraw his rejection of claims 12, 14, 26, and 28.

**c. Claims 13 and 27**

The Examiner rejects claims 13 and 27 under 35 U.S.C. § 103(a) as having been obvious over the combination ASTM F 562-02 and Cockcroft, and further in view of U.S. Patent No. 4,474,733 to Susukida et al. ("Susukida"). The Examiner argues that Susukida suggests adding 5 - 500 ppm calcium to improve hot workability.

Claims 13 and 27 depend from claims 1 and 21, respectively, and add the limitation that the alloy includes 5 - 20 ppm calcium. The Examiner relies on the combination of ASTM F 562-02 in view of Cockcroft to establish all of the constituents of the claimed alloys but for the recited calcium content. The Examiner apparently concludes that Susukida would have suggested further modifying the alloy compositions in ASTM F 562-02 to include the recited calcium contents.

The Examiner's rejections cannot be maintained. First, Applicants have shown above that the Examiner has not established a *prima facie* case that the alloys recited in

claim 1 and claim 21 would have been obvious. The addition of Susukida does not remedy this. Since the Examiner has not been established that the inventions of claims 1 and 21 would have been obvious (and since the additional reliance on Susukida does not change this), it follows that the alloys recited in claims 13 and 27 also have not been shown to be unpatentable.

Second, Susukida would not have motivated or suggested to one of ordinary skill to include 5 - 50 ppm calcium in an alloy having the composition as recited in ASTM F 562-02. Susukida is directed to a heat resistant nickel base alloy consisting essentially of nickel, 0.001 - 0.15 wt. % carbon, 0.0005 - 0.05 wt. % calcium, 20.0 - 26.0 wt. % chromium, 4.7 - 9.4 wt. % cobalt, 5.0 - 16.0 wt. % molybdenum, and 0.5 - 4.0 wt. % tungsten. This composition dictates that the Susukida alloy includes about 40 - 77 wt. % nickel. In contrast, the ASTM F 562-02 alloy at least about 29 wt. % cobalt (see above) and a maximum nickel content of 37.0 wt. %. The Susukida alloy differs so substantially from the ASTM F 562-02 alloy that one would not look to Susukida for teachings in any way pertinent or useful to modifying the alloy. Viewed in another way, given the substantial compositional differences, one of ordinary skill would not perceive in the teachings of Susukida any motivation or a suggestion to modify the alloy of ASTM F 562-02 in any way.

In addition, the passage at column 3, lines 23-32 of Susukida's states the following regarding the rationale for the addition of calcium in the alloy of Susukida:

Calcium is contained in the alloys of the invention in an amount from 0.0005 to 0.05 percent. The calcium contributes to improvement in the hot workability, cold workability, high temperature tensile strength and high temperature fatigue strength of the alloys. If contained in less than 0.0005 percent, it cannot fully perform its proper action, whereas in excess of 0.05 percent, the resulting alloy has markedly poor hot workability. Therefore, the calcium content has been limited to a range from 0.0005 to 0.05 percent.

This passage explains that the reason that calcium is added to the Susukida alloy is to improve workability and high temperature mechanical properties. In contrast, as discussed above, it is believed that the addition of low levels of calcium to the alloys of the Subject Application is advantageous in that it helps to inhibit the formation of titanium nitride and other problematic inclusions, while producing well-tolerated oxide inclusions. Based on the above passage, one would not have looked to Susukida for teachings having the objective of reducing problematic inclusions.

Susukida, at column 3, lines 49-61, also includes the following relevant teaching regarding the concentration of cobalt in the Susukida alloy:

The alloys of the invention contain cobalt in an amount from 4.7 to 9.4 percent, preferably from 6.5 to 9.4 percent. The cobalt acts to enhance the high temperature strength properties of the alloys. If contained in less than 4.7 percent, desired strength-enhancing results cannot be obtained. On the other hand, if contained in excess of 9.4 percent, the resulting alloy has room temperature strength which is too high, remarkably deteriorating the cold workability of the alloys. Thus, the cobalt content has been limited to a range from 4.7 to 9.4 percent. Best high temperature strength properties are available if the cobalt content is within a range from 6.5 to 9.4 percent.

Regarding the above passage, one must consider Susukida for all that it teaches and cannot pick and choose among the various teachings in the reference to establish an obviousness rejection. See *In re Wesslau*, 353 F.2d 238, 241 (CCPA 1965) ("It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art."). Thus, the Examiner cannot extract from Susukida its teaching regarding the addition of calcium, while ignoring the above teaching regarding the required level of cobalt.

The above passage from Susukida clearly teaches away from including cobalt in an alloy in excess of 9.4 wt. %. In contrast, the alloy of ASTM F 562-02 includes at least about 29 wt. % cobalt, while the alloy recited in claims 1 and 21 of the Subject Application includes at least 20 wt. % cobalt. A motivation to combine references in an obviousness rejection has been found absent when one of the references relied upon points in a direction different from the claimed invention. The Federal Circuit, for example, has repeatedly recognized that proceeding contrary to the accepted wisdom in the art is "strong evidence of unobviousness". See, e.g., *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986). The above teaching regarding cobalt would suggest modifying the cobalt concentration of the ASTM F 562-02 alloy so that it does not exceed 9.4 wt. %, which would not result in an alloy as recited in either of claims 1 and 21.

Moreover, so modifying the ASTM F 562-02 alloy composition to limit cobalt content to 9.4 wt. % would presumably destroy the intended functionality of the ASTM F 562-02 alloy, which is impermissible. See *In re Fritch*, 972 F.2d 1260, 1265 n.12 (Fed. Cir. 1992 ("A proposed modification [is] inappropriate for an obviousness inquiry when the modification render[s] the priori art reference inoperable for its intended purpose.")).

For at least the foregoing reasons, Applicants respectfully submit that the Examiner should withdraw his rejection of claims 13 and 27.

**d. Claims 15 and 29**

The Examiner rejects claims 15 and 29 under 35 U.S.C. § 103(a) over the combination of the ASTM F 562-02 and Cockcroft, and further in view of U.S. Patent No. 3,787,202 to Mueller et al. ("Mueller"). The Examiner argues that Mueller teaches adding up to 0.12 wt. % cerium to improve hot workability.

Claims 15 and 29 depend from claims 1 and 21, respectively, and add the limitation that the alloy includes 5 - 50 ppm cerium. The Examiner relies on the combination of ASTM F 562-02 in view of Cockcroft to establish all the components of the claimed alloy compositions but for the recited cerium content. The Examiner apparently concludes that Mueller would have suggested further modifying the alloy compositions of ASTM F 562-02 to include the recited cerium contents.

First, Applicants have shown above that the Examiner has not established a *prima facie* case that the alloys recited in claims 1 and 21 would have been obvious. The addition of Mueller does not remedy this. Since claims 1 and 21 have not been shown to have been obvious over the combination of ASTM F 562-02 and Cockcroft, and since Mueller does not change that fact, it follows that claims 15 and 29 also are patentable.

Second, Mueller would not have motivated or suggested to one of ordinary skill including 5 - 50 ppm cerium in an alloy having the compositions recited in ASTM F 562-02. Mueller is directed to a particular high temperature corrosion resistant chromium-nickel alloy, and the benefits of cerium addition espoused by Mueller are expressly drawn to that particular alloy. As stated in column 2, lines 3-5, of Mueller: "The benefits achieved by the addition of cerium are obtained in a chromium-nickel alloy having at least 45 percent chromium and at least 45 percent nickel." This dictates that no more than 10 wt. % of the Mueller alloy is composed of elements other than chromium and nickel. In contrast, the ASTM F 562-02 alloy includes no more than 21.0 wt. % chromium, no more than 37.0 wt. % nickel, and at least about 29 wt. % cobalt. Clearly, the composition of the Mueller alloy is substantially different from the alloy of ASTM F 562-02. As such, one would not have looked to Mueller for teachings on possible modifications to the ASTM F 562-02 alloy.

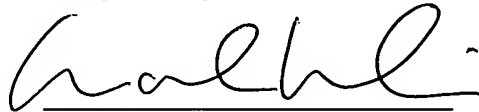
For at least the foregoing reasons, Applicants respectfully submit that the Examiner should withdraw his rejection of claims 15 and 29.

### CONCLUSION

Applicants have made a diligent effort to fully respond to the Office Action and hereby traverse all rejections presented. Applicants respectfully submit that claims 1-34 of the Subject Application, as amended herein, are in condition for allowance. Applicants further submit that new claims 50 and 51 are allowable. Applicants respectfully request issuance of a Notice of Allowance at an early date.

Applicants' present response should not in any way be taken as acquiescence to any of the specific assertions, statements, etc., presented in the Office Action not explicitly addressed herein. Applicants reserve the right to specifically address all such assertions and statements in subsequent responses

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Mark R. Leslie', written over a horizontal line.

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